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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Fredrik Nilsson

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EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,097	Applicant(s) NILSSON, FREDRIK	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 12, 15, 16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 14, 17, 18, 21 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 19, 2007 has been entered.

Status of the Claims

2. Claims 38-39, 44, and 47 were canceled in the amendment to the claims received on February 15, 2006.

Claims 22-23, 28-37, 40-43, 45-46, and 48-49 were canceled and claims 1-2, 7, 9, 10, 14, 21, and 24-27 were amended in the amendment to the claims received on August 25, 2006.

The amendment to the claims received on November 19, 2007 amended claim 1.

Claims 1-21 and 24-27 are currently pending.

Claims 1-11, 13-14, 17-18, 21, and 24-27 are currently under consideration.

Election/Restrictions

3. Applicant elected, with traverse, antibody as the species of binding molecule, C-terminal motif as the species of motif, and at least 10% as the species of capture in the reply filed on February 15, 2006. Claims 12, 15-16, and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

Priority

4. The present application claims priority to U.S. provisional application 60/454,229 filed March 12, 2003.

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, provisional application 60/454,229, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Please refer to the new matter rejection below regarding the limitation "wherein more than one peptide, protein or peptide fragment binds to each defined location on the array" added in the claim amendment received on November 19, 2007. Thus, the presently claimed invention is denied the benefit of the filing date of U.S. provisional application 60/454,229.

Invention as Claimed

6. A method for analyzing a heterogeneous sample of peptides, or protein or peptide fragments, the method comprising (a) separating the heterogeneous sample of peptides, or protein or peptide fragments, into heterogeneous classes by binding members of each class to a spaced apart defined location on an array, wherein more than one peptide, protein or peptide fragment binds to each defined location on the array, and wherein members of each class have a motif common to that class; and (b) characterizing the peptides, or protein or peptide fragments, in each class by determining the mass of the peptides, or protein or peptide fragments in the heterogeneous classes, and determining the abundance of peptides, or protein or peptide fragments, of different mass in the heterogeneous classes and variations thereof.

Claim Objections

7. Claims 1-11, 13-14, 17-18, 21, and 24-27 are objected to because of the following informalities:

A. Claim 1, throughout and claim 2, lines 1-2 read “heterogeneous sample of peptides, or protein or peptide fragments,..”. “[H]eterogeneous sample or peptides, protein fragments, or peptide fragments” or “heterogeneous sample of peptides, proteins, protein fragments, or peptide fragments” is suggested.

B. Claim 1, throughout; claim 7, throughout; claim 9, line 2; claim 10, line 3; claim 21, line 2; and claim 24, line 2 read "...peptide(s), or protein or peptide fragment(s)...". “[P]eptide, protein fragment, or peptide fragment” is suggested.

C. Claim 1, line 10 reads “heterogenous”. “[H]eterogeneous” is suggested.

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D. Claims 2-6 and 14 have "claim" capitalized within the body of the claim. Lower case is suggested.

E. Claim 26 contains "a" from a previous amendment (i.e. August 25, 2006; line 2). Deletion of "a" is suggested.

F. Claim 27, lines 2-3 reads "heterogeneous fragmented or unfragmented samples of peptides, or protein or peptide fragments...". "[H]eterogeneous fragmented or unfragmented samples of peptides, protein fragments, or peptide fragments" is suggested.

Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-11, 13-14, 17-18, 21, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

The claim amendment received on November 19, 2007 added the following text to independent claim 1: "wherein more than one peptide, protein or peptide fragment binds to each defined location on the array, and". However, applicants failed to point out support for the claim amendment in the originally filed specification (please refer to MPEP § 2163.06). Furthermore,

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the examiner of record did not find support for the claim amendment in the originally filed specification (i.e. more than peptide, protein or peptide fragment bound to each class “area” of the array).

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3, 6, 8, 14, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 3 and 6 recite the limitation "the heterogeneous sample of fragments" in lines 2. There is insufficient antecedent basis for this limitation in the claim. “[T]he heterogeneous sample of peptides, protein fragments, or peptide fragments” is suggested.

B. Claims 8 and 14 recites the limitation "the sample" in line 1 and line 3, respectively. There is insufficient antecedent basis for this limitation in the claim. “[T]he heterogeneous sample of peptides, protein fragments, or peptide fragments” is suggested.

C. Claim 14 recites the limitation "the unfragmented sample" in lines 3 and 5. There is insufficient antecedent basis for this limitation in the claim. Dependency on claim 3 and modification of claim 3 to include a limitation that all of the members of the heterogeneous sample of proteins or peptides are not fragmented is suggested. Please note: applicants are cautioned that no new matter may be added.

D. Claim 14 recites the limitations “the peptides” and "the proteins or peptides" in lines 3 and 5, respectively. There is insufficient antecedent basis for this limitation in the claim.

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Dependency on claim 3 and modification of claim 3 to include a limitation that all of the members of the heterogeneous sample of proteins or peptides are not fragmented is suggested.

Please note: applicants are cautioned that no new matter may be added.

E. Claims 25 and 26 recite the limitation "the parent protein or peptide" in lines 2. There is insufficient antecedent basis for this limitation in the claim. Dependency on claim 3 and modification of claim 3 to include a limitation that the heterogeneous sample of proteins or peptides to be fragmented are the parent protein or peptide is suggested.

F. Claims 25 and 26 recite the limitation "the unfragmented heterogeneous sample" in line 3. There is insufficient antecedent basis for this limitation in the claim. Dependency on claim 3 and modification of claim 3 to include a limitation that all of the members of the heterogeneous sample of proteins or peptides are not fragmented is suggested. Please note: applicants are cautioned that no new matter may be added.

G. Claim 26 recites the limitation "the detected protein or peptide fragment" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. Modifying claim 1, method step (b) to include detection is suggested.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. Claims 1-11, 13-14, 17-18, 21, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Nelson et al. U.S. Patent 6,887,713 (effective filing date of March 11, 2000).

For present claim 1, Minden et al. teach methods of identifying a protein via assigning (i.e. separating) binding reagents to designated locations on an array, detecting the binding patterns, and comparing the binding pattern to a reference set (i.e. characterizing; please refer to the abstract, paragraphs [0005-0012], [0028-0032], [0035-0044], [0072-0074], [0077], [00117], Figures 1-11, and Table 1). In addition, Minden et al. teach that the molecular weight or mass of the binding reagents can be determined and that spectrometry can be utilized (please refer to paragraphs [0003-0004], [0030], [0036], [0048]; Figures 7-9). Furthermore, Minden et al. teach that more than one protein can have the same epitope thus the common epitopes (i.e. more than one) would bind to the same defined location (please refer to Figures 4A-4C and 5 and paragraphs 89-96).

For present claim 2, Minden et al. teach that the total protein content of a cell or tissue can be utilized as the protein mixture (please refer to paragraphs [0035], [0066]).

For present claims 3-6, Minden et al. teach that the protein mixture can be fragmented with various chemical or enzymatic methods including trypsin (please refer to paragraph [0037-0039], [0066], [00105], [00107], and Table 1).

For present claims 7-8 and 11, Minden et al. teach that trypsin cleavage forms a peptide or epitope (i.e. motif) with C-terminal lysine or arginine residues (please refer to Table 1 and paragraphs [0041-0045], [0049], [0054], [0063]).

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For present claims 9-10, Minden et al. teach that the peptides or epitopes (i.e. motifs) can be at least three amino acids in length and can have at least two variable amino acids (please refer to paragraphs [0029], [0032], [0040-0046], [0054], [00113-00116]).

For present claim 13, Minden et al. teach that arrays can have different binding molecules at spatially addressable locations which bind to different binding reagents (please refer to paragraphs [0005], [0008], [0012], [0028], [0040]).

For present claim 14, Minden et al. teach that the protein mixture may comprise all (i.e. at least 10% of the peptides) of the proteins and that the epitopes cover the binding mixture (please refer to paragraph [0035], [0040]).

For present claim 17, Minden et al. teach that the array can have 2-100 different proteins (please refer to paragraphs [0047], [0073-0074]).

For present claim 18, Minden et al. teach that the binding reagents can be antibodies (please refer to paragraphs [0029], [0056-0061], [0072]).

For present claim 21, Minden et al. teach that the proteins are compared to a reference set (i.e. characterizing; please refer to paragraphs [0005], [0028-0031], [0040]).

For present claim 25, Minden et al. teach that the reference set can include prediction about binding based on the predicted digests of a protein mixture (i.e. unfragmented, not physically fragmented; please refer to paragraph [0031]).

For present claim 27, Minden et al. teach that various binding reagents can be compared to a reference set or to other binding reagents (please refer to paragraphs [0005], [0030-0031], [0040], [0053]).

However, Minden et al. does not specifically teach determining the abundance of the proteins by the use of desorption mass spectrometry or collision induced dissociation mass spectrometry.

For present claims 1, 24, and 26, Nelson et al. teach analyzing complex biological mixtures utilizing “lab-on-a-chip” (i.e. chip-based microarrays) and MALDI-TOF (i.e. combination of both desorption mass spectrometry and collision induced dissociation mass spectrometry) wherein the proteins are quantified (i.e. abundance), internal reference standards are utilized, and determining the amount (i.e. abundance) of the proteins (please refer to the entire specification particularly the abstract; Figures 1, 4, 7, 8a-c, and 10a-c; column 1, lines 54-67; columns 2-3; column 4, lines 1-30; column 6, lines 52-67; column 8, lines 19-64; column 9, lines 13-35; columns 10-11 and 14-15; column 16, lines 1-10; column 17, lines 30-45).

The claims would have been obvious because the substitution of one known element (i.e. mass spectrometry providing mass information only) for another (i.e. mass spectrometry providing both mass and abundance information; MALDI-TOF) would have yielded predictable results to one of ordinary skill in the art at the time of the invention and/or (b) the claim would have been obvious because a particular known technique (i.e. MALDI-TOF utilized to determine mass and abundance of proteins) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

Therefore, the teaching of Minden et al. and Nelson et al. render the presently claimed invention *prima facie* obvious.

Maintained Rejection

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In addition, the text of the rejection may have been altered to reflect the claim amendment received on November 19, 2007.

Claim Rejections - 35 USC § 103

15. Claims 1-11, 13-14, 17-18, 21, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Barry et al. WO 0225287 (filed September 19, 2001).

For present claim 1, Minden et al. teach methods of identifying a protein via assigning (i.e. separating) binding reagents to designated locations on an array, detecting the binding patterns, and comparing the binding pattern to a reference set (i.e. characterizing; please refer to the abstract, paragraphs [0005-0012], [0028-0032], [0035-0044], [0072-0074], [0077], [00117], Figures 1-11, and Table 1). In addition, Minden et al. teach that the molecular weight or mass of the binding reagents can be determined and that spectrometry can be utilized (please refer to paragraphs [0003-0004], [0030], [0036], [0048]; Figures 7-9). Furthermore, Minden et al. teach that more than one protein can have the same epitope thus the common epitopes (i.e. more than one) would bind to the same defined location (please refer to Figures 4A-4C and 5 and paragraphs 89-96).

For present claim 2, Minden et al. teach that the total protein content of a cell or tissue can be utilized as the protein mixture (please refer to paragraphs [0035], [0066]).

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For present claims 3-6, Minden et al. teach that the protein mixture can be fragmented with various chemical or enzymatic methods including trypsin (please refer to paragraph [0037-0039], [0066], [00105], [00107], and Table 1).

For present claims 7-8 and 11, Minden et al. teach that trypsin cleavage forms a peptide or epitope (i.e. motif) with C-terminal lysine or arginine residues (please refer to Table 1 and paragraphs [0041-0045], [0049], [0054], [0063]).

For present claims 9-10, Minden et al. teach that the peptides or epitopes (i.e. motifs) can be at least three amino acids in length and can have at least two variable amino acids (please refer to paragraphs [0029], [0032], [0040-0046], [0054], [00113-00116]).

For present claim 13, Minden et al. teach that arrays can have different binding molecules at spatially addressable locations which bind to different binding reagents (please refer to paragraphs [0005], [0008], [0012], [0028], [0040]).

For present claim 14, Minden et al. teach that the protein mixture may comprise all (i.e. at least 10% of the peptides) of the proteins and that the epitopes cover the binding mixture (please refer to paragraph [0035], [0040]).

For present claim 17, Minden et al. teach that the array can have 2-100 different proteins (please refer to paragraphs [0047], [0073-0074]).

For present claim 18, Minden et al. teach that the binding reagents can be antibodies (please refer to paragraphs [0029], [0056-0061], [0072]).

For present claim 21, Minden et al. teach that the proteins are compared to a reference set (i.e. characterizing; please refer to paragraphs [0005], [0028-0031], [0040]).

For present claim 25, Minden et al. teach that the reference set can include prediction about binding based on the predicted digests of a protein mixture (i.e. unfragmented, not physically fragmented; please refer to paragraph [0031]).

For present claim 27, Minden et al. teach that various binding reagents can be compared to a reference set or to other binding reagents (please refer to paragraphs [0005], [0030-0031, [0040], [0053]).

However, Minden et al. does not specifically teach determining the abundance of the proteins by the use of desorption mass spectrometry or collision induced dissociation mass spectrometry.

Barry et al. teach methods of determining the binding and mass of trypsin digested proteins including antibodies from a cell including phage or tissue sample immobilized on an array (please refer to the abstract, pages 2-6, 21-30, Figures 3-6 and 8-10, Examples 2-3).

For present claim 1, Barry et al. teach determining the abundance of proteins via MALDI-TOF (i.e. mass; please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

For present claim 24, Barry et al. teach MALDI-TOF (i.e. matrix assisted laser desorption ionization-time of flight) mass spectrometry (i.e. combination of both desorption mass spectrometry and collision induced dissociation mass spectrometry or CID; page 35, line 7; please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

For present claim 26, Barry et al. teach determining the abundance of the protein via MALDI-TOF including proteins from any given starting material (i.e. unfragmented parent

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protein; please refer to page 3, lines 28-30; pages 5-6; page 32, lines 25-33; page 33, lines 21-37; pages 34-35; Figures 3-6 and 8-10, Examples 2-3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al.

One having ordinary skill in the art would have been motivated to do this because Barry et al. teach that the use of mass spectrometry and MALDI-TOF provide semi-quantitative and quantitative results for protein microarrays (please refer to page 1, lines 20-26 and 34-37; page 2, lines 1-24; page 3, lines 5-30; Examples 2-3).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al. because of the examples provided by Barry et al. show that trypsin digested antibody arrays can be quantitated via MALDI-TOF (please refer to Examples 2-3).

Therefore, the modification of the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al. render the instant claims *prima facie* obvious.

Arguments and Response

16. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Barry et al. WO 0225287 (filed September 19, 2001) for claims 1-11, 13-14, 17-18, 21, and 24-27 was considered but was not persuasive for the following reasons.

Applicant contends that the method of Barry et al. would not tolerate incomplete separation because Barry et al. utilizes homogenous classes at each array location (see page 8, first full paragraph); Minden et al. did not contemplate determining the abundance of proteins in the heterogeneous method (see page 8, second full paragraph); the presently claimed method does not require advanced knowledge of the identity of individual proteins in a protein sample; and one of skill in the art would not have had a reasonable expectation of success in determining the abundance of a heterogeneous class of polypeptides via MALDI-TOF merely because Barry et al. taught that one could determine the abundance of a homogenous class of polypeptides.

Applicant's argument is not convincing since the combined teachings of Minden et al. and Barry et al. do render the method of the instant claims *prima facie* obvious.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, both Minden et al. and Barry et al. discuss utilizing mass spectrometry in methods of identifying proteins (i.e. utilizing mass spectrometry in both homogenous and heterogeneous methods). See Minden et al. paragraphs 3-4 and 136 and Barry et al. pages 33-35.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. no previous knowledge of the composition of the peptides or proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.

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1993). In addition, Minden et al. teach heterogeneous protein mixtures including proteolytic cleavage of proteins (please refer to paragraphs 29-35). Furthermore, Minden et al. teach that the protein mixture can be all of the proteins in a given organism, proteome, organ, tissue, cell, organelle, or sub-cellular localization and thus all of the proteins are not necessarily known.

Regarding applicant's assertion that one of ordinary skill would not have had a reasonable expectation of success, it is also noted that (a) the claim would have been obvious because the substitution of one known element (i.e. mass spectrometry providing mass information only) for another (i.e. mass spectrometry providing both mass and abundance information; MALDI-TOF) would have yielded predictable results to one of ordinary skill in the art at the time of the invention and/or (b) the claim would have been obvious because a particular known technique (i.e. MALDI-TOF utilized to determine mass and abundance of proteins) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Please also refer to the reasons of record in the rejection (see above).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Amber D. Steele/
Patent Examiner, Art Unit 1639

February 11, 2008